Delaware Public Health Laboratory BT update



October 2013

Debbie Rutledge, MBA MT(ASCP)

Bioterrorism Lab Coordinator



### CDC Select Agent Program

- "Select agents and toxins are a subset of biological agents and toxins that the Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products".
- CDC oversees the Select Agent Program (SAP), which regulates the laboratories which may possess, use, or transfer select agents within the US.
- Established by USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, enacted after September 11, 2001 attacks and the 2001 anthrax attacks.



#### **DPHL**

- 10/ 2012, CDC SATP updated regulations
  - Tiering of select agents
  - Suitability assessments-Credit, personality,etc
  - Increased security and safety- Intrusion detection systems
  - 15 minute response time
  - DPHL chose to not maintain Tier 1 agents
  - Does not affect our ability to confirm Select agents- destroy in 7 days



# The Laboratory Response Network





## LRN Coverage





#### LRN PYRAMID



#### The Laboratory Response Network

Level DLab BSL-4

Level CLab BSL-3

Level B Lab BSL-2 facility+ BSL-3 safety practices

> Level ALab Operate at BSL-2

D - Highest level characterization (Federal)

C - Molecular assays, reference capacity

B – Confirmation or referral

A - Rule-out and forward organisms

# Biosafety Level 3 lab





#### **Bioterrorism testing**

- BT agents
  - Bacillus anthracis, Brucella sp., Francisella tularensis, Yersinia pestis, Burkholderia sp.
  - Coxiella, Varicella, Orthopox,
  - Ricin, Clostridium botulinum
- Unknown FBI Screening Protocol –Powders, letters and environmental samples- 7 target agents
- Clinical samples blood, sputum, bronchial washings, cerebral spinal fluid
- Clinical isolates from microbiology labs
- Post office specimens



#### Influenza & Resp. Virus

- Influenza A
- Influenza B
- H1N1, H3N2, H3N2v
- H7N9- new strain, seen in China 2013
- H5N1- avian flu
- Middle Eastern Respiratory Syndrone-(MERS CoV) 4/2013
- Respiratory Virus Panel 12 viruses



# Foodborne Disease Testing

- Salmonella
- Shigella
- Vibrio
- Listeria
- Shigatoxin E.coli
- Norovirus
- Bacillus cereus
- Staphylococcus aureus
- Bioterrorism & toxin agents in food or clinical specimens



#### Infectious Disease testing

- Pertussis
- Measles
- Mumps
- Mycobacterium tuberculosis complex(MTB)
- BT agents (naturally occurring)- Brucella, Francisella, coxiella, varicella, etc.
- Arbovirus- EEE, WNV
- For more information visit our webpage http://www.dhss.delaware.gov/dph/lab/labs.html



# Microbiological cultures



14



### PHEP Funding

- 2005- present
  - BSL 3+ lab & equipment
  - Culture vs. Molecular testing 2-3 days to 2 hrs
  - Laboratory Information Management System (LIMS) & HL7 reporting
  - DNA fingerprinting (Pulsed Field Gel Electrophoresis (PFGE)) PulseNet & CaliciNet
  - Molecular Sequencing- unknown organisms
  - Increased security, registration, monitoring & background checks



#### **Exercises and Outreach**

- Full Scale Exercises Operation Loose Package
- Sentinel lab training- wet workshops
- HazMat Conference & Preparedness Summit
- Association of Public Health Laboratories (APHL)
   Annual Meeting and Environmental Laboratory
   Conference
- Biannual Lab Preparedness Advisory Committee (LPAC)
- LabWeek Open House Joint with EMSPS
- First responder's and chain of custody training
- Packaging & shipping for infectious materials



#### **CDC** improvements

- New labs & equipment
- LRN –Standardized protocol & reagents
- Surge capacity in the network
- Emergency Use Authorization (EUA)-
  - 1st used for H1N1
  - Bypass FDA approval for validation of new methods
  - State labs- able to confirm w/in 7 days
  - Using for new threats now (MERS-CoV, H7N9)



# **Questions or Comments?**

